

Remarks

Claims 1-22 are pending. The Examiner withdrew from consideration as part of a restriction requirement claims 11-17. The Applicants have added claim 22; support for this new claim may be found at paragraph [0060].

The Applicants address the Examiner's remarks in the order he presented them.

Objections to the specification

The Applicants have amended the specification to correct the typographical errors the Examiner identified.

The Rejection under § 112, second paragraph

The Examiner rejected claims 6, 10, and 18-21 under 35 U.S.C. § 112, second paragraph. The Applicants have amended claims 6, 10, and 18, and respectfully submit that all the rejected claims now comport with the requirements of § 112. They respectfully request that the Examiner withdraw the rejection under this section.

The rejection under § 112, first paragraph

The Examiner rejected claim 10 under 35 U.S.C. § 112, first paragraph. The Applicants respectfully submit that their amendments to claim 10 address the Examiner's rejection under this section. They respectfully request that he therefore withdraw it.

The first § 102 rejection

The Examiner rejected claims 1-3 and 10 under 35 U.S.C. § 102(e) in view of Nakanishi *et al.* (U.S. Patent No. 6,235,521). The Examiner argues that Nakanishi *et al.* discloses a SV40-gpD fusion protein that anticipates the claims. The Applicants respectfully disagree.

The claims of the present application are directed to a fusion protein comprising a membrane-penetrating peptide attached to a compound of interest. There is nothing to suggest that the SV-gpD fusion protein, in contrast, is a membrane-penetrating peptide. It therefore cannot support a rejection under

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**§ 102(e).**

The Examiner states that the SV-gpD fusion protein "contains a nuclear localization signal"; that it "comprises the amino acid sequence Arg-His-Lys-His" (Office Action, at 5); and so on, but none of these facts establish that the Sv-gpD fusion protein is a membrane-penetrating protein. Indeed, the Examiner does not even *allege* this to be the case.

The Examiner appears to be arguing that because Nakanishi *et al.* describes the SV-gpD fusion protein as containing a nuclear localization signal, the fusion protein therefore comprises a membrane-penetrating peptide. But a protein that contains a nuclear localization signal is not necessarily a membrane-penetrating peptide, as the Inventors' work makes clear. See, e.g., present application, at ¶ 0048 ("like many putative NLSs that do not always confer nuclear localization when fused to reporter sequences, any potential MPPs must be functionally determined experimentally") (citations omitted) and ¶ 0046. And while it is true that in preferred embodiments, membrane penetrating peptides "may be derived from an NLS [nuclear localization signal], or overlapping with an NLS," present application, at ¶ 0052, this very fact *distinguishes* membrane penetrating peptides from nuclear localization signals (how can one thing be "derived" from another if they are both the same thing?).

The Applicants respectfully submit that because Nakanishi *et al.* does not disclose a membrane-penetrating peptide, it fails to disclose each and every limitation of the claims, and, hence, cannot support a rejection under § 102(e). The Applicants therefore respectfully request that the Examiner withdraw the rejection under this section.

**The second § 102 rejection**

The Examiner rejected claims 1-3, 7-10, and 18-21 under 35 U.S.C. § 102(b) in view of Guarante *et al.* (Molec. Cell Bio., 578-585, Vol. 7, No. 2. (1987)). The Examiner states that Guarante *et al.* discloses "a yeast fusion protein that comprises a nuclear localization signal, derived from a transcription factor." Office Action, at 5. The Applicants respond as they do above: the fact that a protein contains a nuclear localization signal does not mean that it also contains a membrane penetrating peptide. Indeed, the facts do not establish that the fusion protein of Guarante *et al.*

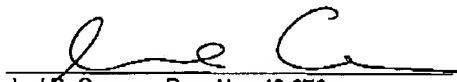
is a membrane penetrating peptide, and, indeed, the Examiner does not even allege otherwise.

The Applicants respectfully submit that because Guarente *et al.* does not disclose or suggest all the limitation of the claims, the reference cannot support a rejection under § 102(b). The Applicants respectfully request that the Examiner withdraw the rejection under this section.

**Conclusion**

The Applicants respectfully submit that the claims, as amended, are in condition for allowance, and respectfully request early, favorable action on the application. Should the Examiner believe that an interview would advance the prosecution of this application, the Applicants invite him to contact the undersigned at (908) 231-3444.

Respectfully submitted,



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